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Part IV

Council on Environmental Quality

Report to the President by the Toxic Substances Strategy Committee

COUNCIL ON ENVIRONMENTAL QUALITY

Toxic Substances Strategy Committee Report to the President

August 13, 1979.

ACTION: Request for Comments on the Report to the President by the Toxic Substances Strategy Committee.

SUMMARY: The Toxic Substances Strategy Committee (TSSC), an interagency committee established by the Council on Environmental Quality at the direction of the President, has prepared a draft of its Report to the President. This Report presents the findings, policy considerations, and tentative recommendations reached by the TSSC in its deliberations and study which began in October 1977. The draft is being issued for review and comment so that the final Report to the President may reflect the full range of public comments and concerns.

The Report contains six substantive chapters: Federal Chemical Information Systems; the Treatment of Confidential Information; Research Activities That Support Regulation; Response to Chemical Emergencies; Regulatory Programs and Their Coordination; Cancer and Carcinogens: Preventive Policy; and International Issues. The Executive Summary for the 200-page Report appears below.

Comments are sought and encouraged on all issues and recommendations addressed in the draft Report.

It should be stressed that the findings and recommendations contained in the draft Report, while carefully developed and debated within the TSSC, do not necessarily represent the final views of the individual agencies participating in this effort. The public comments received, along with additional agency review of the draft, will assist the several agencies in formulating their final recommendations to the President.

DATE: Comments on the draft Report must be received by September 30, 1979.

ADDRESS: Requests for the report should be addressed to the Public Information Office (TSSC-Report), Council on Environmental Quality, Executive Office of the President, 722 Jackson Place, N.W., Washington, D.C. 20006.

Comments or requests for futher information should be directed to: Robert B. Nicholas, Senior Staff member for Environmental Health and Toxic Substances, Council on Environmental Quality, 722 Jackson Place, N.W., Washington, D.C. 20006. Telephone: (202) 395–4980.

Gus Speth,

Chairman, Council on Environmental Quality (Chairman, Toxic Substances Strategy Committee).

Executive Summary

Purpose of the Toxic Substances Strategy Committee and This Report

The vastly increased production and use of chemicals and chemical products since World War II and their pervasiveness in our surroundings have led to growing concern over their effects on human health and the environment. Initially, the Federal Government engaged primarily in ad hoc reactions to major incidents or discovery of widespread damage. Increasingly, however, it is moving toward a more deliberate and comprehensive effort with prevention as the major control strategy. President Carter is committed to such a strategy, and legislation now provides regulatory tools for reducing or eliminating the hazards posed by toxic substances from before commercial production until after disposal.

This comprehensive control effort requires increased knowledge about the chemicals in commerce, including their mixtures, byproducts, uses, persistence and fate in the environment, and the possible effects of exposure on humans, plants, animals, and ecosystems. Equally important is improvement in ways of minimizing the risks posed by the much smaller number of these substances that are hazardous.

President Carter recognized the extraordinary effort that is required to address toxic substances problems and to respond to the mandates of recent legislation. In his Environmental Message of May 23, 1977, he instructed the Council on Environmental Quality (CEQ) to develop and interagency program to eliminate overlaps and fill gaps in collection of data on toxic chemicals and to coordinate federal research and regulatory activities affecting them.

The Toxic Substances Strategy Committee (TSSC) was formed in response. It includes representatives of all federal departments and agencies with major policy, research, or regulatory responsibilities relating to control of potentially hazardous chemicals. The Committee has evaluated the adequacy and appropriateness of current federal activities relating to toxic substances, including those of its own member agencies and other interagency groups such as the Interagency Regulatory Liaison Group, the National Toxicology Program, and the Interagency Toxic Substances Data Committee.

The TSSC focused on several study areas related to research, data and information, and prevention and control strategies that could be addressed fruitfully in a short time. Other concerns were excluded from consideration as a matter of practicality and in recognition of special considerations pertaining to the excluded subjects that are not applicable to other aspects of toxic substances control. Thus cancer was given more attention than other health effects, for example; and regulatory approaches to toxic substances control were given more immediate attention than voluntary or educational measures. The TSSC also excluded concerns relating exclusively to radiation hazards, physical safety hazards, nutrition, tobacco, and alcohol.

Following transmittal of this report to the President, the TSSC will continue long enough to initiate planning for individual agencies and interagency groups to implement the recommendations.

The Toxic Substances Problem (Chapter I)

Most chemicals, chemical mixtures, and chemical products are relatively harmless under safe and normal conditions of use and exposure. Most are extremely beneficial and modern society has come to depend upon them. But the result is extensive exposure to chemical substances, including those whose effects on human health and environment are often detrimental.

Human exposure to toxic substances [1] may occur through air, water, and terrestrial pollution; through pesticides, foods and food additives, drugs, cosmetics, consumer products, workplace conditions, waste disposal, and accidents. Human health effects include cancer, birth and other reproductive anomalies, neurological and behavioral disorders, kidney damage, lung and heart disease, acute and chronic skin disease, acute poisoning, and many others.

Perhaps the most serious source of human exposure to toxic chemicals is

[1] "Toxic" is a relative term. The effects of any chemical substance or mixture depend not only on its composition and basic properties but also on dosage, route and conditions of exposure, susceptibility of the organism exposed, and other factors. It is therefore impossible to categorize all chemical substances as "toxic" and "non-toxic," although some are more toxic than others during normal conditions of use and exposure, and some are generally innocuous. In this report "toxic substances" is not intended to be a scientifically precise term but to encompass the principal concerns of the federal activities here addressed.

the workplace. More than 100,000 workers are believed to die each year as a result of physical and chemical hazards at work, but the magnitude of the long-term health effects of occupational conditions is unknown. Occupational exposure to carcinogens is a factor in an estimated 20 to 38 percent of all cases of cancer. An unknown number of persons are at risk because of hazardous chemicals seeping into water supplies from the thousands of hazardous waste dump sites across the nation, and because of many other types of exposure, from cosmetics to breakfast food.

The magnitude of the toxic substances control problem is almost overpowering in view of the number of substances whose risks should be evaluated, the rate of growth in both number and volume of chemicals, the various routes by which humans and the environment are exposed, possible synergistic or combined effects among the substances, and the effects that they cause–acute and chronic, immediate and delayed.

More than 43,000 chemical substances are listed by the Environmental Protection Agency (EPA) in its initial inventory of substances that are produced commercially in significant amounts and that are subject to regulation under the Toxic Substances Control Act of 1976 (TSCA). This does not include chemical mixtures and foods, drugs, cosmestics, pesticides and other substances not subject to TSCA. Years of research can be required to determine if a particular substance is hazardous.

Consideration of which hazards to control and how and when to control them requires difficult judgments about relative risks and about the costs and benefits of control—judgments that involve complex health, environmental, social, economic, technological, and legal factors. Many of the relevant factors cannot be estimated with certainty, and often an objective and commonly agreed upon method for considering them is not available.

The personnel, equipment, and financial resources that are available both publicly and privately for toxic substances control (including research, testing, monitoring, information exchange, control programs, and response to emergencies) are small in relation to the job to be done. Until recently, nearly everyone seems to have underestimated the magnitude of the research, data, regulatory, and enforcement tasks involved.

In response to growing concern over toxic substances problems, Congress has enacted over two dozen regulatory statutes, covering the various means by which toxic chemicals can threaten human health and the environment. The laws are administered primarily by six agencies.[2] The existence of these laws reflects society's conclusion that the unregulated market does not adequately protect human health and the environment from potential hazards from chemical substances, especially when the hazards are subtle, chronic or delayed.

The Toxic Substances Strategy Committee has consluded that the basic approach and structure of these laws are sound. Particularly appropriate is their preventive approach. Prevention is the key to controlling diseases and environmental problems caused by toxic chemicals. Public health and the environment will be adequately protected from chemical hazards only with the direct government action to regulate releases and exposures. Most of the statutes employ a precautionary principle, mandating action to limit exposure to a potentially hazardous substance when evidence of the hazard is convincingly suggestive, but not completely certain.

However, implementation of these laws has been slow. Measured against the need, the handful of chemicals regulated to date have been disappointingly small. Budgetary support for federal toxic substances control recently increased, expecially for implementation of TSCA. Nevertheless, EPA's Office of Toxic Substances does not expect to catch up with the backlog of existing hazards for many years, and some new hazards may enter the market despite the screening process established under TSCA.

Despite these limitations, many past problems are being overcome, particularly in regard to interagency coordination. Many steps have recently been taken by individual agencies and interagency groups to increase the information base and to make better use of and disseminate available data, to coordinate the testing of chemicals, to increase the pace and consistency of risk assessment and of regulatory activities, to cooperate actively in chemical emergencies, to exchange information with industry and nonfederal groups, and to pursue international goals for global toxic sustances control.

[2] Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), the Food Safety and Quality Service of the Department of Agriculture, and the Department of Transportation (DOT).

A summary of the major findings and recommendations contained in the report follows.

Federal Chemical Information Systems (Chapter II)

Federal toxic substances control would be facilitated by an integrated network of chemical data systems serving the information needs of all the agencies. Such a system does not now exist. At present, the many agencies involved with toxic substances use over 220 independent data systems, all organized differently, ranging from computer systems to simple manual files. An integrated data network could be used to reduce duplicative information gathering and some delays in decisionmaking. It would be useful to states, industry, public interest groups, international organizations, and foreign governments, as well as to federal agencies.

Federal agencies are also hampered by the lack of a common means of identifying chemicals and chemical uses. Chemicals are identified in different files and publications using chemical structure, various types of chemical nomenclature or numbering systems, and common or generic names.

Another important information need is assurance of the reliability of physical and chemical data contained in the numerous data systems, especially when these are to be linked in a network.

Several interagency groups are addressing these problems. The Interagency Toxic Substances Data Committee, the major forum for these activities, was formed in February 1978 and is now coordinating development and implementation of a Chemical Substances Information Network (CSIN). The CSIN will be a loosely coupled network of data bases relating to chemicals, their production, uses, fate and transport in the environment, and effects.

Part of CSIN is expected to be operational next year, and other major components will be available in 2–5 years. Nevertheless, many complex technical, financial, administrative, and policy details have yet to be worked out. Even with the most diligent development by the Data Committee and the agencies, it may take 10 years for CSIN to be fully operational.

The TSSC places great importance on continuing the recently established interagency coordination mechanisms relating to chemical information. It considers the vigorous development of CSIN by the Interagency Toxic Substances Data Committee to be crucial and urges that CSIN continue to

receive high priority and adequate support from all the agencies concerned.

The best means for identifying chemical substances unambiguously appears to be to assign a unique number to each unique chemical structure. The Data Committee recommended, and the TSSC strongly endorses, expanded use of a computerized numbering system maintained by the Chemical Abstracts Service (CAS), a service of the American Chemical Society. Federal agencies concerned with toxic substances should be required to use the CAS numbering system as the identifier in their files and proceedings, either as the sole identifier or by cross-reference.

The TSSC further recommends that EPA expedite completion of a Chemical Use Classification System and IRLG, completion of a Chemical Regulations and Guidelines System (to provide information on federal, state, foreign, and international regulations and standards affecting particular chemicals). The National Bureau of Standards should be lead agency in establishing standards for physical and chemical data and taking other steps to promote data reliability. Finally, the IRLG should investigate the feasibility of monitoring scientific literature in an organized way for evidence of new or previously unrecognized toxic chemical problems.

The Treatment of Confidential Information (Chapter III)

Treatment of trade secrets and confidential commercial or financial information obtained in connection with toxic substances control programs has emerged in the mid-1970's as a major policy controversy. The controversy is the product of tension between two opposing interests, both recognized by Congress.

On the one hand, regulatory agencies need to collect, share and make public much scientific, technical, and economic information in order to make and explain sound control decisions. On the other hand, the toxic substances laws and certain general statutes such as the Federal Criminal Code and the Freedom of Information Act recognize that businesses have legitimate interests in keeping valuable information secret from competitors. Current federal laws generally provide agencies with the capability to obtain the information needed but because of inconsistencies and gaps do not adequately accommodate this conflict between the public right to know and the business need to protect valuable trade secrets. The conflicts arise over how far these rights should go. For example, most environmental and health laws permit public disclosure of confidential information when it is "relevant" in a regulatory proceeding. However, agencies' policies differ on when, to whom, and under what circumstances data should be disclosed, and on what precautions to employ to prevent further unauthorized disclosure. The laws also vary as to whether confidential data may be shared with other agencies involved in toxic substances programs and as to whether such data may be disclosed to contractors which are helping an agency assess a toxic substances problem.

Current federal laws generally do not permit agencies to share confidential information with state regulators, despite their major responsibilities for protecting public health. Nor do the laws generally allow citizens access to confidential information concerning chemical hazards to which they may be personally exposed, on the job or elsewhere. Other laws impede epidemiological research by protecting the confidentiality of medical records. Finally, different rules and procedures apply in different agencies and under different statutes not just with regard to how to treat confidential data, but in regard to whether or not information should be classified as confidential in the first place.

The Toxic Substances Strategy Committee established the Subcommittee on Trade Secrets and Data Confidentiality to consider these problems. The Subcommittee examined the confidentiality provisions of 14 major toxic substances control statutes to determine their approaches to interagency data sharing, sharing of data with contractors, public disclosure of confidential health, safety, and efficacy data, and disclosure of confidential information in administrative proceedings. The Subcommittee's findings and conclusions are:

• *Interagency sharing of confidential data.* Interagency sharing of confidential data will facilitate research and regulatory action, eliminate duplicative efforts, and increase agency access to necessary information.

Inadvertent disclosure resulting from interagency sharing, a problem of concern to industry, can be prevented through employing security measures. Models for ensuring adequate security have been developed by EPA and the IRLG. The TSSC recommends that the Interagency Toxic Substances Data Committee prepare legislation to remove barriers to sharing of confidential data between health and environmental agencies. The legislation should provide for security of the data transferred, impose penalties for the unauthorized disclosure of confidential data, and establish transfer procedures which include at least 10 days notice to the data submitter prior to transfer.

• *Sharing of confidential data with agency contractors.* Sharing of confidential data with expert contractors is essential for efficient agency implementation of health and environmental protection laws. The Interagency Toxic Substances Data Committee in consultation with the affected agencies should propose legislation permitting such sharing for all relevant agencies similar to the authority contained in TSCA and FIFRA. The legislation should require adoption of security procedures and penalties similar to those discussed in terms of interagency sharing in order to protect against inadvertent disclosure and other misuse of data. Procedures already in use by some agencies should be uniformly adopted to prevent possible misuse of data because of conflicts of interest.

• *Disclosing health, safety, and efficacy information.* The public's strong interest in (1) obtaining information on potentially toxic chemicals in products, in the workplace, and the environment in order to balance the benefits of exposure to substances against the risks in their own daily lives, and (2) participating in and reviewing government decisions, favors routine disclosure of health, safety, and efficacy data. Routine disclosure of this information could also be of substantial value to the scientific community because it assures peer review of test methods and data, reduces needless duplication of research, and advances scientific knowledge. However, health, safety, and efficacy data may represent a substantial investment and provide a competitive edge, particularly when the data have been produced to satisfy a premarket license requirement. Routine disclosure of such data could discourage innovation and competition. The TSSC therefore recommends that legislation be developed by the Interagency Toxic Substances Data Committee in consultation with affected agencies that allows public access to confidential data on a "good cause" public interest standard. The legislation should include security precautions, sanctions for unauthorized further disclosures, and notice to the data submitter. TSSC further recommends that agencies release detailed summaries where they do not have authority to release the data itself.

• *Disclosing confidential information in administrative proceedings.* The extent to which confidential information used in otherwise open administrative adjudications or rulemaking proceedings is disclosed to the parties or the public is generally left to agency discretion. The TSSC recommends, in order to ensure effective public participation in proceedings and to allow full explanation of agency decisions, that agencies develop uniform policies to provide for disclosure, without breaching confidentiality, as for example, by releasing of "sanitized" versions of data when possible. Since sanitizing data is not always possible, the Interagency Toxic Substances Data Committee should propose legislation that provides for disclosures on a good-cause public interest basis in a proceeding, and for enforceable sanctions against unauthorized further disclosures.

Research Activities That Support Regulation (Chapter IV)

Toxic substances regulation cannot be undertaken in a vacuum. Regulatory decisions to control toxic substances should be based on facts and figures as to potential harmful effects on human health or the environment, on the extent of the population at risk, on the availability and effectiveness of control alternatives, on modes of transmission and interactions in the evironment. Yet obtaining all the data needed to regulate toxic substances in the U.S. is a mammoth task. It is not yet known even how many of the tens of thousands of chemicals in commerical use pose toxic hazards, much less in what amounts and under what circumstances. Testing for toxicity is a lengthy and expensive process and requires trained personnel. Thus the information available on chemicals whose effects are in question is often fragmentary and incomplete.

Given the limitations on government resources and the fact that it is industry which is introducing most new chemical substances into use, much of the scientific and technical information used in agency decisionmaking today is industry generated. Only a small portion is produced through government research, testing or monitoring programs. It is thus critical that the government use what research capabilities it has as effectively and efficiently as possible. Its resources are needed both to assess hazards about which little data are available anywhere, and to assess the adequacy and accuracy of industry-generated data, and supplement it where necessary.

The TSSC surveyed federal toxic substances research, testing, and monitoring programs to determine their scope, means of coordination and exchange of information, and methods of evaluation and to identify research areas needing increased emphasis or more scientific or technical personnel. TSSC's overall concern was whether research activities adequately support regulation and whether they are well coordinated.

In addition to its own survey, which was led by the National Science Foundation, the TSSC reviewed efforts to coordinate research planning in the IRLG, the National Toxicology Program (NTP), the Task Force on Environmental Cancer and Heart and Lung Disease, the Interagency Testing Committee, and the Interagency Task Force on Data and Monitoring.

The TSSC found that some 37 federal agencies conduct or support toxic-related research, with budget obligations totaling more than $640 million in FY 1977. They are sponsoring research on dispersion of toxic chemicals in the environment, human exposures and effects, mechanisms of actions, aquatic ecological effects, terrestrial ecological effects, control technologies, combined programs, and miscellaneous other subjects.

These agencies were found to face problems of shortages of qualified scientific and technical personnel, and of resources to undertake long-term research. Long-term research usually requires 3–5 years or more to evaluate serious issues or hazards. Available resources are often taken up by the need to make regulatory decisions in the face of emergencies or newly discovered problems.

Other problems with federal research efforts include the difficulties of coodinating research planning among the many regulatory and research agencies, the lack of centralized information describing all research projects in progress, and the need to ensure scientific quality.

The TSSC recommends that the current high level of commitment to research, monitoring, and testing be continued. However, five topics should be given increased emphasis in the FY 1981 and subsequent budgets: terrestrial ecology, social and economic impacts of toxic substances and their regulation, epidemiology, toxicology, and control technology.

The agencies responsible for toxic substances regulation should develop proposals for building and sharing the scientific and technical capabilities needed to evaluate information adequately that is used in regulation. They should also explore the need for additional legislative authority to conduct research or technical activities.

The TSSC found no compelling need at this time for an overall toxic substances research coordinating committee. Rather, the IRLG agencies and the National Toxicology Program (NTP) should continue their coordination efforts, and the NTP should consider adding new areas of toxic substances research and testing to its program. The TSSC further recommends that agencies supporting toxic substances research submit timely and complete information on their research projects to the Smithsonian Science Information Exchange or its successor, and that the IRLG encourage interagency sharing of peer review mechanisms and resources. In order to overcome personnel shortages, the TSSC recommends that EPA, the National Institute for Environmental Health Sciences, and the National Institute for Occupational Safety and Health develop proposals within 12 months for a federal retraining and education program in environmental health and environmental pollution control technology.

Response to Chemical Emergencies (Chapter V)

Spills and other incidents involving release of hazardous substances create serious health and environmental emergencies. Many such spills require an extremely fast response as for example, the derailment of a railroad car carrying toxic gas which has escaped. Decisions must be made accurately and rapidly on the nature of the problem and how to insure effective containment, clean-up and disposal, and monitoring of long-term effects. Other releases involve the gradual accumulation of toxic substances and unless abated, become emergencies with the passage of time, for example the leaching of toxic wastes from hazardous waste disposal sites. Although the exact number of spills is unknown, estimates prepared for EPA for all non-oil chemicals project an annual average of 2,216 spills in excess of 100 gallons each year from 1978 through 1982.

The Nation is not currently organized to deal effectively with all such emergencies. The private sector is primarily responsible under law for cleanup of hazardous substances spills and releases. Many large chemical companies and transporters are organized to respond to emergencies. However, many smaller manufacturers and transporters are not.

When industry fails to clean up a spill, the Government must take over. Most State and local emergency response plans and funds for paying for clean-up are inadequate. The Federal EPA and U.S. Coast Guard have the authority and capability to send in expert response teams, track down perpetrators, offer technical assistance and organize a cleanup. However, Federal efforts to respond to these emergencies have been hampered by overlapping authorities, by disputes over what and how substances should be designated hazardous for purposes of extending this kind of aid and by the absence of contingency funds for spills on land.

The Government also does not have adequate funds or mechanisms for providing relief or compensation to victims of a spill or for cleanup of abandoned waste sites.

The TSSC established a Subcommittee on Chemical Emergencies to look into these problems. The Subcommittee worked closely with the EPA Task Force on Environmental Emergencies, which during the same period was examining EPA's ability to respond to such situations. The TSSC found that private and Government ability to respond to spills could be improved through better contingency planning, through better response procedures, and through establishment of contingency funds. The TSSC recommendations are as follows:

• *Contingency Planning.* The National Contingency Plan coordinates all Federal efforts in the event of a spill of oil or a designated hazardous substance in navigable water. The TSSC recommends that this be expanded to cover environmental emergencies on land as well. In addition, provisions should be added regarding follow-up on environmental and health damages, both acute and chronic. The TSSC further recommends that EPA and DOT develop guidelines for State contingency planning; and that EPA and the Coast Guard develop guidelines for industry plans for responding to spills, accidents and other releases.

• *Federal Response.* The TSSC recommends that EPA and DOT regularize and make uniform their requirements for reporting of spills; that a single source of timely, accurate, uniform, and complete information on a substance be established within the Chemical Substances Information Network (CSIN) for use in emergencies; that EPA with other agencies develop a plan for doing quick assessments for substances not adequately covered by the system above; and that EPA develop standards for cleanup and site restoration in the event of a spill.

• *Superfund Legislation.* The TSSC recommends adoption of the proposed Oil, Hazardous Substances, and Hazardous Waste Response, Liability and Compensation Act to provide contingency funds for the Federal Government to respond to and clean up inactive hazardous waste disposal sites and spills, whether on land or water, and provide some compensation to victims for economic losses.

• *Training.* EPA and the Coast Guard should combine their training efforts and give a single Federal training course to State environmental officials who will direct emergency responses. In addition, EPA and DOT should work with the National Fire Prevention and Control Academy to provide special training to firefighters in handling of hazardous substances.

• *Prevention.* The TSSC recommends that EPA and the Department of Justice should continue their efforts under relevant laws to require cleanup of spills by responsible parties. They should also consider and make recommendations for improving the cost recovery mechanisms authorized by Section 311 of the Clean Water Act. EPA, DOT, and the Small Business Administration should explore the feasibility of establishing tax or other incentives for small companies to improve their capabilities for responding to emergencies.

Regulatory Programs and Their Coordination (Chapter VI)

Over two dozen laws, some of them overlapping, grant authority for federal regulation of toxic chemicals.

The multiplicity of approaches resulting from the variety of statutory requirements has positive effects. It reflects real differences in the types of toxic substances problems and their solutions. However, coordination is essential in order to ensure consistency of regulatory actions, efficient use of public and private resources, and attention to the most significant hazards.

On the whole, the TSSC found this legislative authority to be adequate, but in two areas it requires strengthening: authority for uniform liability and compensation for hazardous substances pollution damages, including those from abandoned waste sites (see Chapter V), and coverage of cosmetics, which is currently less comprehensive than for food, drugs, and other chemical substances.

Cosmetic manufacturers are not required to inform the Food and Drug Administration about product ingredients, results of any prior testing, or any adverse reactions reported. Some manufacturers volunteer the information, but with limited access to complete information, the burden of proof is on the government to show that a cosmetic may be injurious as used or that its labeling may be false or misleading. Without either the information or the authority to compel manufacturers to provide it, the determination of risk and the ability to take regulatory action are severely limited.

Despite the statutes and their authorities, regulatory resources are limited compared to the job to be done. Progress has been slow in setting standards and in fulfilling other statutory mandates. The Environmental Protection Agency and the Occupational Safety and Health Administration have set standards for only a handful of air, water, workplace, and drinking water pollutants over the last decade. The regulatory response often seems like a "chemical of the week" approach rather than a planned strategy. Regulation of toxic chemicals will continue to be slow and somewhat ad hoc because of constraints of scientific knowledge, resources, and complexity of the social, economic, political, legal, scientific, and technical factors to be considered.

The regulatory agencies are taking steps to speed the regulatory process and to achieve consistency and coordination among programs. Individual agencies are making use of "generic" policies or regulations, i.e., they are covering similar hazards at once instead of individually, in order to simplify and shorten regulatory proceedings. Collectively, the regulatory agencies are cooperating through the Interagency Regulatory Liaison Group [3] in the development of compatible approaches to screening, testing, and risk assessment, in the development of regulatory standards, compliance and enforcement, and in the use of field personnel and facilities.

A shortcoming in federal regulation is the failure to develop new approaches to the costs and benefits of regulation. Many of the laws and agency policies regarding toxic chemicals regulation calls for some consideration of these factors; for some hazards the laws require adequate protection of human health "to the extent feasible." Some agencies use cost-benefit analysis as one of several tools in making decisions; others consider present methods and data bases too limited to do so.

[3] The IRLG is composed of EPA, OSHA, CPSC, and the Food Safety and Quality Service of the Department of Agriculture.

The benefits of regulation—pain not suffered, lives not lost—are especially difficult to quantify. Another practical difficulty is how to handle uncertain but suggestive evidence of harmful effects of substances. Further, benefits may be underestimated if the total costs of regulating a substance are compared to only the one hazard that is the subject of the particular regulation, rather than to the effects from the chemical's entire life cycle.

Costs are also difficult to estimate. They may be over-estimated if long run adjustments in the economy are not considered—such as substituting less risky substances for the one being regulated. On the other hand, they may be underestimated if possible adverse effects of alternative substances are not anticipated, or if the indirect costs associated with disruption to the industry are ignored.

Despite inherent limitations of cost-benefit analysis in general and the errors and omissions that are frequently made when cost-benefit analysis is applied to toxic substances regulation, improvements in analytical methods will help the agencies to select consistent and cost effective ways to reduce risks—i.e., to achieve the greatest protection of human health and the environment that is possible with available resources.

Recognizing that coordination of toxic substances programs is necessary to make efficient use of available resources, the TSSC recommends that the IRLG agencies identify the stage and aspects of the regulatory process for which closer coordination would be desirable and most cost effective. Certain present IRLG activities should be continued and expanded: developing regulations for selected chemicals of common interest; defining new research initiatives; developing common approaches to risk assessment; developing compatible testing standards and guidelines; and encouraging interaction among the agencies at the Federal, State, and local levels. Further, if the regulatory agencies are to respond fully to the legislative mandate and public health problems posed by toxic chemicals, their resources must be enhanced.

The Regulatory Council in close cooperation with the agencies, is asked to undertake a major effort to improve methods for estimating costs and benefits of regulation and for evaluating them. The TSSC also recommends increased use of generic approaches to identification and assessment of chemical risks, increased funding of public participation in the regulatory process, and development of a coordinated labeling strategy by the IRLG agencies together with the Department of Transportation.

TSSC also urges the Administration to develop and support legislation for strengthened cosmetic regulation, including authority for the Food and Drug Administration to obtain test data and other information from industry and including an increased inspection authority for FDA.

Cancers and Carcinogens: Prevention Policy (Chapter VII)

Cancer is the only major cause of death that has continued to rise since 1900. It is now second only to heart disease as a cause of death and is responsible for the loss of 400,000 lives each year. Infectious diseases have dropped dramatically since the turn of the century, and the average age of the U.S. population has increased. But even after correcting for age, both mortality (deaths) rates and incidence (new cases) are increasing.

It is now recognized that environmental (non-genetic) factors contribute to the great majority of cancer cases seen. Studies show that most cancer cases—perhaps as many as 80 to 90 percent—are not just a legacy of race or genetic heritage but are also a function of cultural and physical environments and of personal habits. Many now believe that a cancer is likely to be the result of several causative agents, some of which are potentially preventable. Cancers also appear to be multi-staged, and various environmental factors may affect different stages in the progression to malignancy.

Studying this group of diseases and their causes is complicated by the fact that typically there is a latency period of 15–40 years between initial exposure to the agent(s) that cause cancer and the clinical appearance of tumors. Epidemiology is and will continue to be an important tool in the study of human cancer risks, but scientists generally agree that animal tests are a valid and essential means of identifying potential human carcinogens. Such tests provide a more rapid and less expensive means of identifying these substances than trying to trace an exposed human population over a 20 year period. Animal tests have suggested that many substances previously thought to be safe are in fact carcinogenic. Nevertheless, most substances are not capable of causing cancer, even when tested at high doses.

Since passage of the National Cancer Act in 1971, the nation's cancer policy has emphasized basic understanding of the basic biological and biochemical bases of cancer; better methods of intervention, diagnosis and treatment; and identification of environmental and genetic causes of cancer. Individuals and groups are exposed to potentially carcinogenic substances through food, the workplace, consumer products, tobacco products, drugs, and air and water pollutants. Regulations of these substances is aimed at reducing or eliminating human exposures.

As federal agencies have begun to regulate exposure to carcinogens in the past decade, recurring problems have arisen determining whether a substance may cause cancer, assessing the cancer risk, establishing regulatory priorities, and taking regulatory action. Virtually all aspects of cancer prevention policy have been extensively examined within the federal government since formation of the TSSC, through the policies and procedures of EPA, OSHA, CPSC, the IRLG Risk Assessment Work Group and others.

Publication by the IRLG agencies of the scientific bases for identification of potential carcinogens and estimation of risk is an important step in achieving consistent agency policies.

Underlying regulatory decisions on potential carcinogens and the agency policies are principles basic to the identification of potential human carcinogens:

- Properly qualified animal tests are accepted as valid ways to identify chemical substances that may cause cancer in humans. Experimental animals, such as mice, rats and hamsters, are appropriate test species and have been used extensively since the 1930s. In all but one or two cases, chemicals that are known to cause cancer in humans have also been found to cause cancer in small rodents. Several substances first identified as causing cancer in rodents have later been confirmed as carcinogenic in humans.
- Established test protocols, which include administration of high test doses, are appropriate and valid methods for identifying potential carcinogens in humans. The intrinsic carcinogenic character of a chemical substance is independent of dose level. High test doses make this characteristic easier to discern.
- Methods do not now exist for determining a "safe" threshold level of exposure to Carcinogens. Uncertainties in the dose-response relationship between specific exposures and cancer risk, unknown factors that influence individual susceptibility to cancer, and unpredictable interactions among cancer-causing agents prevent

determinations of safe levels for human exposure to a carcinogen, however small, is regarded as an addition to the total carcinogenic risk.

• Methods for quantifying the estimated human risks from a given exposure to a potential carcinogen can provide only approximations of the actual risk.

The TSSC recommends that the agencies responsible for the regulation of potential carcinogens continue to identify and evaluate ways to streamline their procedures. Agencies should seek to place the burden of proof on proponents of use or exposure to a substance. The IRLG agencies should seek to adopt generic policies for carcinogens, and establish procedures for taking interim regulatory actions prior to the time-consuming process of establishing permanent standards and regulations, wherever possible under law.

The TSSC further recommends that the IRLG agencies, as well as the National Cancer Institute, the NIEHS and other agencies, should seek to educate the public about policies and procedures that are currently widely misunderstood. These include use of laboratory animal tests to determine potential human carcinogenicity, and the fact that there is no current method for determining a threshold of "safe" level for human exposure to a carcinogen.

International Issues (Chapter VIII)

Toxic substances control problems affect all nations, both industrialized and developing, in their efforts to protect human health and the environment. Especially in view of the new emphasis on prevention, the United States and other industrialized nations share responsibility to provide information and assistance to less developed countries so that they can avoid mistakes made by the industrialized nations. Even countries that may never become chemical producers are often the unwitting recipients of hazardous substances and products exported by countries in which they are banned or are severely restricted.

There is growing recognition of the need to consider toxic substances in a global context. Because many toxic substances cross national boundaries or affect the global commons, they can be controlled only through concerted international action or similar actions by individual nations.

Many governments are developing or have recently enacted laws that provide for assessment of the effects of chemicals in commerce and/or at the premarket stage and for their regulation. These laws have as a common objective the protection of human health and the environment. Countries are concerned that differences in regulation will strain resources (e.g., if one country would not accept test data from another country) or lead to barriers to world trade. Although absolute uniformity of regulatory approaches among countries is not considered possible or desirable, mutual confidence among nations in each other's control measures is essential.

Developing international consistency in toxic substances control is not easy, however. Differences among countries in social, political, economic, cultural, and technological values and experience lead to differences in interpreting scientific data and considering the risks and benefits of control. Impediments to international exchange of information are even greater than those hindering exchange among domestic agencies.

With these difficulties coupled with the fact that most countries are preoccupied with developing toxic substances controls within their own boundaries, it would be tempting to delay international efforts until internal matters stabilize. There are reasons why national and international strategies are and should be proceeding simultaneously: to develop consistent approaches before implementation of individual national control programs will restrict flexibility to do so, to begin early on the many complex issues for which extensive consultations will be required prior to international agreement, and to permit some early agreements to contribute to solutions of other problems in sequence.

The TSSC reviewed recent international toxic substances activities and recommends that the United States continue its vigorous support of efforts to achieve consistency among nations in the control of toxic substances. Consistency is especially important in the areas of good laboratory practices, chemical nomenclature and key terms relating to toxic substances control, and data requirements for new chemicals in international commerce. The Chemicals Program of the Organization for Economic Cooperation and Development (OECD) is singled out for particular support. Additional areas for which improved international cooperation and information exchange should be promoted are the identification of potentially dangerous chemicals and the development of related health and safety data; development of methods for assessing risks and benefits; acquisition of technical information on safe production, use, and waste disposal; and development of ways to respond cooperatively to chemical crises. The results of these efforts should become the basis for agreement on an international convention for toxic substances control.

Additional TSSC recommendations cover more specific needs: obtaining international agreement on notification between governments of hazardous substances exports and on uniform labeling of hazardous substances in international commerce; facilitating sharing among countries of technical information relating to environmental and health effects of toxic substances and their safe production, use, and disposal; obtaining more accurate data on the export and import of chemicals regulated or proposed for regulation; sharing information and developing uniform criteria relating to land and ocean disposal of hazardous wastes; and implementing the provisions of Executive Order 12114 regarding environmental review of certain major government actions that have effects outside the United States.

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***NOTE: As of July 2, 1979, all agencies in the Department of Transportation, will publish on the Monday/Thursday schedule.**

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Rules Going Into Effect Today

ENVIRONMENTAL PROTECTION AGENCY

41429 7-17-79 / Approval and Revision of the Penn. Implementation Plan

List of Public Laws

Last Listing August 13, 1979

This is a continuing listing of public bills from the current session of Congress which have become Federal laws. The text of laws is not published in the **Federal Register** but may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (telephone 202-275-3030).

H.R. 4476 / Pub. L. 96-49 "Higher Education Technical Amendments of 1979" (Aug. 13, 1979; 93 Stat. 351) Price: $.75

H.J. Res. 19 / Pub. L. 96-50 "National Lupus Week" (Aug. 13, 1979; 93 Stat. 356) Price: $.75

H.J. Res. 209 / Pub. L. 96-51 "National Diabetes Week" (Aug. 13, 1979; 93 Stat. 357) Price: $.75

S. 1318 / Pub. L. 96-52 To amend title 13 of the United States Code to provide a limited exemption to the Bureau of the Census from the provisions of section 322 of the Act of June 30, 1932. (Aug. 13, 1979; 93 Stat. 358) Price: $.75

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